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10/802,682

03/17/2004

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(C038435/010970)

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03/27/2007

EXAMINER

WALICKA, MALGORZATA A

ART UNIT

PAPER NUMBER

1652

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE |
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3 MONTHS

03/27/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/802,682

Applicant(s)

ASAKURA ET AL.

Examiner

Malgorzata A. Walicka

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 March 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,9,20-22,25 and 28-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 9 is/are allowed.
- 6) ☒ Claim(s) 1-3,20-22,25 and 28-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application March 12, 2007, after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office Action has been withdrawn pursuant to 37 CFR 1.114.

The examiner acknowledges the Amendment filed March 12, 2007 comprising the amendment's to the claims and REMARKS. Claims 1, 2, 30 and 31 have been amended; the amendment has been entered. Claims 4-8, 10-19, 23-24 and 26-27 were previously canceled. Claims 1-3, 9, 20-22, 25, 28-31 are pending.

Detailed Action

35 USC 112, second paragraph

Claims 1, 2, 3, 20-22, 25 and 29-31 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims recite the phrase "hybridizes under stringent conditions" and "stringent washing conditions" which being indefinite, renders the claim indefinite. There are many sets of hybridization conditions in the prior art that are used for identifying DNA molecules by hybridization, and the choice of a particular set depends on the experimenter and the experimental problem at hand. Different hybridization conditions lead to different selection of DNA molecules. The claims do not explicitly state the conditions which Applicants call "stringent".

Response to Applicants arguments

Applicants in their current REMARKS (page 6, the last line) argue,

"The specification as filed provides details as to how this phrase [stringent hybridization and stringent washing conditions] is to be interpreted, see, e.g. page 16, lines 9-15. For exact details of these hybridization procedures, the specification cites Sambrook et al., Molecular Cloning (2nd ed.), Cold Spring Harbor Laboratory Press 1989, New York. For example Sambrook provides on page 9.52 a complete proteocol for stringent hybridization and stringent washing conditions. A copy of this protocol is attached as Exhibit 1."

Applicants' argument has been fully considered but is found not persuasive for the following reasons.

I. The specification as filed does not provide details as to how this phrase is to be interpreted. Page 16, lines 9-15 of the specification read as follows:

"Standard conditions' for hybridization mean in this context the conditions which are generally used by one skilled in the art to detect specificic hybridization signals and which are described, e.g. by Sambrook et al., 'Molecular Cloning" second edition, Cold Spring Harbor Laboratory Press 1989, New York. Such 'standard conditions' are preferably, stringent hybridization and non-stringent washing conditions, or more preferably stringent hybridization and stringent washing conditions **familiar to those skilled** in the art and which are described, **e.g.**, in Sambrook et al [emphasize added] ."

One having skilled in the art realizes that the quoted passage of the specification does not provide details for stringent hybridization and stringent washing conditions because the phrase "familiar to those skilled in the art" is indefinite since there are many

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sets of stringent hybridization and stringent washing conditions, and what is "familiar" to one experimenter is not necessary familiar to the other. Reference to Sambrook et al. is used in exemplary way, thus quoting Sambrook et al. does not exclude conditions other than presented by Sambrook et al.

II. As to page 9.52 of Sambrook et al., page 9.52 even does not contain the phrase "stringent hybridization and stringent washing conditions". It describes prehybridization solutions, "**appropriate for the task at hand**" [emphasis added], which are suitable "**for detection of low-abundance sequences**" or "**for moderate- or high abundance sequences**".

What task has been at Applicant's hand, and have Applicants detected low abundance sequences or moderate-or high abundance sequences? What have been conditions for hybridization and washing?

35 U.S.C. 112 first paragraph

Scope of enablement

Claims 1-3, 20-22, 25, 28, 30-31 are rejected because the specification, while being enabling for the alcohol and aldehyde dehydrogenases of SEQ ID NO: 5, 6, 7, and 8, is not enabling for the invention as claimed. The disclosure does not teach the stringent hybridization conditions and stringent washing conditions to be used in selection of DNA molecules of invention, claims 1-3, 20-22, 25, 28, 30-31 as amended are not enabled and thus rejected. In addition, claim 2 and 3 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the

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plasmid comprising genes encoding SEQ ID NO: 5 and SEQ ID NO: 8 (plasmids pSSAB201 and pSSBA201), does not reasonably provide enablement for an enzyme that comprises a combination of at least two amino acids sequences each of said sequences being selected from the group of SEQ ID NO: 8 and SEQ ID NO: 5 and amino acid sequences encoded by DNA sequences hybridizing under stringent hybridization conditions and stringent washing conditions DNA molecules according to SEQ ID NO: 4 or 1. The reasons were explained in the previous Office actions.

Response to Applicants' arguments

In their current REMARKS page 8, line 21 Applicants emphasize that Sambrook, on page 9.47 states, that aqueous solutions and solutions of 50% formamide are both solvents that show excellent results, and conclude

"Therefore, the Examiner's statement that 'the disclosure does not teach the hybridization conditions to be used in selection of DNA molecules of [the] invention' in *misplaced*"; emphasis and bracket are added by Applicants.

Applicants' argument has been fully considered but is found not persuasive.

I. The claims do not quote anywhere a solution containing 50% formamide or aqueous solutions, thus referring to them is not to the point.

II. Sambrook et al. on page 9.47 do not refer to one set stringent hybridization conditions and stringent washing conditions ready to be used. Actually they even do not use the phrase "stringent hybridization conditions and stringent washing conditions". What Sambrook et al. do is starting the page with enumerating seven respects in which "many methods available to hybridize" differ. After that Sambrook et al. continue:

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"Although the choice depends to a large extent on personal preference [emphasis added], we offer the following guidelines for choosing among the various methods available."

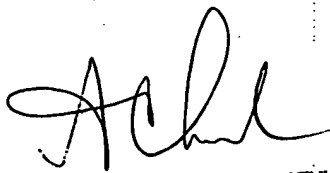
The disclosure is silent as to what was Applicants' personal preference, or which of the various methods available they have chosen.

Conclusion

Claim 9 is allowed for the reasons indicated by the examiner in the First Office Action on merits on Dec. 1, 2004. Claims 1-3, 20-22, 25, 28-31 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Malgorzata A. Walicka, Ph.D., whose telephone number is (571) 272-0944. The examiner can normally be reached Monday-Friday from 10:00 a.m. to 4:30 p.m. If attempts to reach examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, Ph.D. can be reached on (571) 272-1600. The fax phone number for this Group is (703) 305-3014. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionists whose telephone number is (703) 872-9306.

Malgorzata A. Walicka, Ph.D.
Patent Examiner
Art Unit 1652


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